


MAY 28 2004

K041337

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|  PRO WALKER | PRO WALKER INC. No. 60, An Li Lane, Chang An Rd., Tachia, Taichung Hsien. TAIWAN. R.O.C. Tel: +886-4-2682-1799 Fax: +886-2682-1899 Website: www.pro-walker.com.tw E-mail : pro.walker@msa.hinet.net |
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“ 510(k) SUMMARY ”

Submitter's Name: *PRO WALKER INC.*

*No. 60, An Li Lane, Chang An Road, Tachia, Taichung Hsine,
Taiwan, 437, ROC.*

Date summary prepared:

May 12, 2004

Device Name:

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| Proprietary Name: | PRO WALKER ML-300 Foldable Wheelchair |
| Common or Usual Name: | Mechanical Wheelchair |
| Classification Name: | Mechanical Wheelchair, Class I, 21 CFR 890.3850 |

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:


The PRO WALKER ML-300 Foldable Wheelchair is an indoor / outdoor wheelchair that has a base with four-wheeled with a seat. The device can be disassembled for transport and it is foldable easily. The device uses a standard sling type back and seat, the upholstery fabric meets the California Technical Bulletin CAL 117 standard for flame retardant.

Performance Testing:

ML-300 Foldable Wheelchair meet the applicable performance requirements as specified in ANSI/RESNA WC vol. 1 and ISO 7176 Wheelchair Standards as indicated in section B page 7-1~7-5.

Legally marketed device for substantial equivalence comparison:

BIOTECH B900 SUPER LIGHT Wheelchair (K020472).

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Summary for substantial equivalence comparison:

The new device and the predicate device have the same intended use and the weight limit **100kgs** between the two devices is the same. Mainframes of two devices are foldable. The overall dimensions are similar. Back upholstery material is also the same resistance ignitability fabric. The major differences existing of the two Mechanical Wheelchairs are the different overall dimension and weight between the two devices. The overall appearance and weight differences are not safety aspect. So the new device is substantially equivalent to the predicate devices in this aspect.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2004

Pro Walker, Inc.
C/o Dr. Kc-Min Jen
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City, China (Taiwan) 300

Re: K041337

Trade/Device Name: PRO WALKER ML-300 Foldable Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: May 12, 2004
Received: May 19, 2004

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

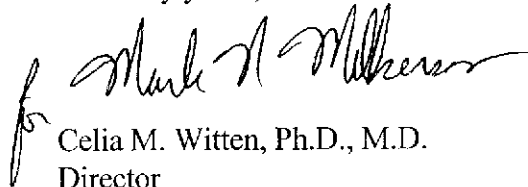
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over a horizontal line. To the left of the signature, there is a small, stylized mark that looks like a lowercase "f" or a checkmark.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (K) NUMBER (IF KNOW): TBA

DEVICE NAME: PRO WALKER ML-300 Foldable Wheelchair

INDICATIONS FOR USE:

The device is intended for medical purposes to provide mobility to person restricted to a sitting position.

Prescription Use _____

AND/OR

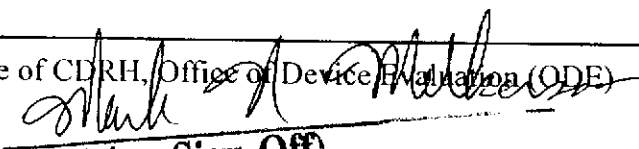
Over-The-Counter Use ✓

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for 
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(K) Number K041337